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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,580	04/15/2004	Anja Kohlrausch	01-1491	8666

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EXAMINER	
FINN, MEGHAN R	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
01/27/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO.e-Office.rdg@boehringer-ingelheim.com

Office Action Summary	Application No.	Applicant(s)	
	10/825,580	KOHLRAUSCH, ANJA	
	Examiner	Art Unit	
	MEGHAN FINN	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,5,9 and 12-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,9 and 12-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2010 has been entered.

Applicants' arguments, filed October 25, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicant's Terminal Disclaimer filed October 25, 2010 has been approved. Thus the double patenting rejection over 6,737,432 has been withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-5, 9, and 12-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hauel et al. (US 5,591,762) in view of Dinnebier et al. (Journal of Pharmaceutical Sciences, 2000, Vol. 89 (11), pages 1465-1479), in further view of Vippagunta et al. (Advanced Drug Delivery Reviews, 2001, vol. 48, pages 3-2), each already of record in office actions dated April 23, 2010 and July 30, 2009 the reasons of which are hereby incorporated by reference, in further view of newly cited Sharpe et al. (Telmisartan: A Review of its Use in Hypertension).

Claims 1-2, 4-5, 9, and 12-20 were previously rejected over Hauel et al. in view of Dinnebier et al. and Vippagunta et al. Applicant has argued that the references do not teach 30-90mg of crystalline telmisartan sodium salt and hydrochlorothiazide. Applicant specifically focuses on Hauel et al. and examples 230 and 232, which are a tablet with 100mg telmisartan and an oral suspension of 50mg of telmisartan. While it is the examiner's opinion that the combination of Hauel et al., Dinnebier et al. and Vippagunta et al. render the claims unpatentable there is further evidence that these

dosages are obvious. In the interest of greater clarity to and further show that dosages that read upon applicant's 30-90mg range were known in the art, Sharpe et al. is cited. Sharpe et al. teaches that combinations of telmisartan at 40mg or 80mg per day with hydrochlorothiazide 12.5mg/day have been shown to be more effective than each agent alone and are effective in treating hypertension (page 1505, 4th paragraph). They specifically teach 40mg/day in a tablet form (page 1509, column 1, 4th paragraph). They do not teach the crystalline salt, however as discussed previously at length Dinnebier et al. teaches three crystalline forms of telmisartan (abstract) and teaches that polymorphism can affect the chemical, biological and pharmaceutical properties of a drug (page 1465). Vippagunta et al. teaches that those differences in physical properties can have an important effect on the processing of a drug and the differences in solubility can have an effect on the absorption of the active drug (page 4). The same crystalline from claimed is taught by Dinnebier et al., so its properties are known and one of ordinary skill in the art at the time of the invention would be able to evaluate the known forms of crystalline telmisartan and pick the one best suited towards their particular use. As discussed previously, it would have been obvious to use a crystalline form of the sodium salt in Hauel et al. and Hauel et al. teaches dosages of 100mg as well as 50mg. They teach tablets and capsules (column 57) and thus a tablet or capsule at 50mg is obvious regardless of whether their example 232 is an oral suspension or not. However, there is even further evidence that it would have been obvious to make a tablet at 40mg because of the teachings of Sharpe et al. which teach a specific combination of 40mg telmisartan and 12.5mg HCTZ. These have already

been tested in the art and found to be effective for treating hypertension and it would have been obvious to one of ordinary skill in the art at the time of the invention that tablets containing 40mg telmisartan are effective for the composition of Hauel et al. Thus claims 1-2, 4-5, 9, and 12-20 are unpatentable over Hauel et al. in view of Dinnebier et al., in further view of Vippagunta et al. in further view of Sharpe et al.

Applicant's arguments towards the previous rejection were solely directed towards whether Hauel et al. teaches 30-90mg and the fact that the oral suspension in example 232 is not a tablet or capsule. The disclosure of Hauel et al. is not limited to only the exemplary embodiments such as example 232; they do not have to have an example of that combination in order to teach it. They clearly teach dosages in the claimed range and they clearly teach both tablet and capsule forms. See MPEP 2123. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In *re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab*, LLC, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005). These arguments are not found persuasive because the fact that Hauel et al. teaches both the dosages

and the dosage forms, along with Sharpe et al. which teaches exact dosage/form that reads upon those claimed renders the claims obvious to one of ordinary skill in the art.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 7:30am-5pm Mon-Thu, 7:30am-4pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1614